



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Continuous subcutaneous insulin infusion (CSII or 'insulin pumps') for people with type 1 and gestational diabetes
Topic exploration report number:	TER127

Introduction and aims

HTW researchers searched for evidence on continuous subcutaneous insulin infusion (CSII or 'insulin pumps') for people with type 1 diabetes or women with gestational diabetes. There was an emphasis on finding evidence which compares the clinical and cost-effectiveness of individual CSII devices.

Summary of findings

NICE has published guidance on CSII devices for people with type 1 diabetes (TA151) and for diabetes in pregnancy (NG3) recommending use of the technology in certain circumstances. These publications do not compare outcomes between individual devices. TA151 and NG3 were published in 2008 (last reviewed 2014) and 2015 (last reviewed 2018) respectively.

Two Cochrane reviews and several more systematic reviews were identified comparing CSII to multiple daily injections (MDIs). Whilst these are relevant to the topic area they do not compare the clinical and cost effectiveness of different CSII devices. No reviews were identified which compared outcomes between individual CSII devices. One protocol for an ongoing systematic review was identified which may compare outcomes for individual devices although this is not clear.

Evidence

NICE guidance

From [Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus: Technology appraisal guidance \[TA151\]](#) Published date: 23 July 2008

1.1 Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:

- attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia.

or

- HbA1c levels have remained high (that is, at 8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

1.2 CSII therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:

- MDI therapy is considered to be impractical or inappropriate, and
- children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.

1.5 CSII therapy is not recommended for the treatment of people with type 2 diabetes mellitus.

NICE describes the following insulin pump models as currently available (costs from 2008):

- Animas 2020 (Animas, Johnson & Johnson, cost £2600)
- Paradigm real-Time mmT-522 (Medtronic, cost £2750)
- Paradigm real-Time mmT-722 (Medtronic, cost £2750)
- Accu-Chek Spirit (Roche Diagnostics, cost £2375)
- Accu-Chek D-Tron Plus (Roche Diagnostics, cost £996)
- Deltec Cozmo (Smiths Medical, cost £2750).

No evidence was identified in the NICE guidance which compared CSII devices against one another.

From [Diabetes in pregnancy: management from preconception to the postnatal period NICE guideline \[NG3\]](#) Published date: February 2015

1.3.16 Offer women with insulin-treated diabetes continuous subcutaneous insulin infusion (CSII; also known as insulin pump therapy) during pregnancy if adequate blood glucose control is not obtained by multiple daily injections of insulin without significant disabling hypoglycaemia

From [Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes \(the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system\)](#) Diagnostics guidance [DG21] Published date: February 2016

1.1 The MiniMed Paradigm Veo system is recommended as an option for managing blood glucose levels in people with type 1 diabetes only if:

- they have episodes of disabling hypoglycaemia despite optimal management with continuous subcutaneous insulin infusion and
- the company arranges to collect, analyse and publish data on the use of the MiniMed Paradigm Veo system (see section 7.1).

NICE has produced a Medtech Innovation Briefing [on MiniMed 640G system with SmartGuard for managing blood glucose levels in people with type 1 diabetes](#)

These technologies are likely to have progressed since publication of these NICE documents.

No other HTAs were identified.

Systematic reviews

Two relevant Cochrane reviews were identified.

[Farrar et al \(2016\)](#) studied CSII versus MDI of insulin for pregnant women with diabetes. Five studies were included with 153 women and 154 pregnancies. There is no evidence to support the use of one particular form of insulin administration over another for pregnant women with diabetes. The authors noted that pump technology has progressed since the included trials were undertaken.

[Misso et al. \(2010\)](#) looked at CSII versus multiple insulin injections for type 1 diabetes. Twenty three studies randomised 976 participants with type 1 diabetes to either continuous subcutaneous insulin infusion or multiple injections. There is some evidence to suggest that CSII may be better than MDIs for glycaemic control in people with type 1 diabetes.

These studies did not compare individual CSII devices against each other.

A Medline search retrieved 47 systematic reviews relating to CSII for diabetes. Most appear to compare CSII to MDI and do not compare devices which may be of limited relevance given the questions from the topic referrer. Seven of these reviews included some form of economic evaluation.

Ten ongoing systematic review protocols with potential relevance to CSII for diabetes were identified. One appeared particularly relevant in terms of comparison between devices. Pease et al. (2018) describe the objective of the review as “to determine if any currently available technology utilised in managing adults with type 1 diabetes is superior to other technologies or to insulin injections and capillary blood glucose testing for achieving improved glycaemic control, lower risk of complications, superior quality of life and more favourable cost-effectiveness”. However, it is unclear whether the review will compare across classes of technologies or individual brands.

Areas of uncertainty

No systematic reviews, health technology assessments or evidence-based guidelines were identified which compare individual CSII devices against one another. An issue to consider is that the technology progresses quickly and published evidence may become out of date.

Conclusions

There is considerable evidence on the use of CSII devices compared to MDIs in people with type 1 diabetes and in women with gestational diabetes. NICE recommends the technology in certain people. However, no sources of secondary evidence were identified comparing the clinical- and cost-effectiveness of specific CSII devices against one another.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant evidence from this source.
Health Technology Assessment Group	Paediatric Care Model recommends use of CSII based on NICE guidance, but does not recommend particular pumps. There are some criteria that pumps must be able to achieve for certain patient types.
Health Information and Quality Authority	We did not identify any relevant evidence from this source.
UK guidelines and guidance	
SIGN	SIGN 116 Management of Diabetes is based on NICE recommendations, but has no information on the choice of pump.
NICE	<p>Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus: Technology appraisal guidance [TA151] Published date: 23 July 2008</p> <p>Diabetes in pregnancy: management from preconception to the postnatal period: NICE guideline [NG3] published Feb 2015</p> <p>Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system) Diagnostics guidance [DG21] Published date: February 2016</p> <p>MiniMed 640G system with SmartGuard for managing blood glucose levels in people with type 1 diabetes Medtech innovation briefing [MIB51] Published date: February 2016</p>
Secondary literature and economic evaluations	
EUnetHTA	No information identified
Cochrane library	<p>2 systematic reviews identified that compared CSII to multiple daily injections of insulin: Farrar D, Tuffnell DJ, West J, West HM. Continuous subcutaneous insulin infusion versus multiple daily injections of insulin for pregnant women with diabetes. Cochrane Database of Systematic Reviews 2016, Issue 6. Art. No.: CD005542. DOI: 10.1002/14651858.CD005542.pub3.</p> <p>Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J. Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD005103. DOI: 10.1002/14651858.CD005103.pub2.</p>
Medline	47 systematic reviews were identified related to CSII technology in diabetes. Most appear to compare CSII to MDI and do not compare devices. 7 of these reviews appeared to include an economic evaluation.

Ongoing primary or secondary research	
PROSPERO database <i>Check for recent systematic review protocols.</i>	21 ongoing systematic review protocols were identified, of which 10 were relevant to CSII technology in diabetes. The following systematic review protocol is particularly relevant: Pease, A., Lo, C., Earnest, A., Liew, D., & Zoungas, S. (2018). Evaluating optimal utilisation of technology in type 1 diabetes mellitus from a clinical and health economic perspective: protocol for a systematic review . <i>Systematic reviews</i> , 7(1), 44.

Date of search:	November 2019
Concepts used:	Insulin pump, insulin infusion, continuous insulin infusion pump